

**REMARKS**

This Application has been carefully reviewed in light of the Office Action mailed January 25, 2007. At the time of the Office Action, Claims 138-140, 142-148 and 152-155 were pending in this Application. Claims 138-140, 142-148 and 152-155 were rejected. Applicant respectfully requests reconsideration and favorable action in this case in light of the following remarks.

**Withdrawn Rejections**

Applicant thanks the Examiner for withdrawing all outstanding rejections under §§ 102 and 103.

**Objection to Specification**

The Office Action has objected to the specification as allegedly unclear as to which amendments find support in the specification as filed. Applicant has prepared the following chart to assist the Examiner in reviewing the specificaiton amendments that have been made.

<b>1. Amendment to Page 25, Line 13 to Page 27, Line 9</b>			
<b>Date</b>	<b>Spec Change</b>	<b>Support</b>	<b>Objection</b>
Response filed August 2, 2005, to OA Dated 02/03/05.	The invention contemplates the use of a broad range of pharmaceutical compounds. Non-limiting examples include hormones, hormone antagonists, analgesic, antipyretics, antiinflammatory drugs, immunoactive drugs, antineoplastic drugs, antibiotics, anti-inflammatory agents, sympathomimetic drugs, anti-infective drugs, anti-tumor agents, and anesthetics. Further non-limiting examples include drugs that target or effect the gastrointestinal tract, liver, cardiovascular system, and respiratory system. Further non-limiting examples of pharmaceutical compounds include insulin, heparin, calcitonin, ampicillin, octreotide, sildenafil citrate, calcitriol, dihydrotachysterol, <b>ampomorphine</b> , <b>apomorphine</b> ,	Applicant respectfully asserts that support for the correct spellings of each pharmaceutical would have been apparent to one of ordinary skill in the art. <i>See also</i> Response filed August 2, 2005.	Objection withdrawn in OA mailed 05/17/06

**1. Amendment to Page 25, Line 13 to Page 27, Line 9**

Date	Spec Change	Support	Objection
	<u>yohimbine</u> , <u>trazodone</u> , <u>trazadone</u> , acyclovir, amantadine·HCl, rimantadine·HCl, cidofovir, delavirdine·mesylate, didanosine, famciclovir, <u>forsearnetfoscarmet</u> sodium, fluorouracil, ganciclovir sodium, idoxuridine, interferon- $\alpha$ , lamivudine, nevirapine, penciclovir, ribavirin, stavudine, trifluridine, valacyclovir·HCl, zalcitabine, zidovudine, indinavir·H <sub>2</sub> SO <sub>4</sub> , ritonavir, nelfinavir·CH <sub>3</sub> SO <sub>3</sub> H, saquinavir·CH <sub>3</sub> SO <sub>3</sub> H, d-penicillamine, chloroquine, hydroxychloroquine, aurothioglucose, gold sodium thiomalate, auranofin levamisole, <u>DTCdacarbazine</u> , isoprinosine, methyl inosine monophosphate, muramyl dipeptide, diazoxide, hydralazine·HCl, minoxidil, dipyridamole, isoxsuprine·HCl, niacin, nylidrin·HCl, phentolamine, doxazosin·CH <sub>3</sub> SO <sub>3</sub> H, prazosin·HCl, terazocin·HCl, clonidine·HCl, nifedipine, molsidomine, amiodarone, acetylsalicylic acid, verapamil, diltiazem, nisoldipine, isradipine, bepridil, isosorbide-dinitrate, pentaerythrytol-tetranitrate, nitroglycerin, cimetidine, famotidine, nizatidine, ranitidine, lansoprazole, omeprazole, misoprostol, sucralfate, metoclopramide·HCl, erythromycin, bismuth compound, alprostadil, albuterol, pirbuterol, terbutaline·H <sub>2</sub> SO <sub>4</sub> , salmetrol, aminophylline, dyphylline, ephedrine, ethynorepinephrine, isoetharine, isoproterenol, metaproterenol, <u>n-deeromilnedocromil</u> , <u>oxytriphyllineoxtriphylline</u> , theophylline, bitolterol, fenoterol, budesonide, flunisolide,		

**1. Amendment to Page 25, Line 13 to Page 27, Line 9**

Date	Spec Change	Support	Objection
	beclomethasone-dipropionate, fluticasone-propionate, codeine, codeine sulfate, codeine phosphate, dextromethorphan·HBr, triamicinolone-acetonide, montelukast sodium, zafirlukast, zileuton, cromolyn sodium, ipratropium bromide, nedocromil sodium benzonate, diphenhydramine·HCl, hydrocodone-bitartrate, methadone·HCl, morphine sulfate, acetylcysteine, guaifenesin, ammonium carbonate, ammonium chloride, antimony potassium tartarate, glycerin, terpinhydrate, colfosceril palmitate, atorvastatin·calcium, cervastatin·sodium, fluvastatin·sodium, lovastatin, pravastatin·sodium, simvastatin, picroorrhiza <b>kurrvakkurroa</b> , andrographis paniculata, moringa oleifera, albizzia lebeck, <b>adhataadhatoda</b> vasica, curcuma longa, momordica charantia, gymnema sylvestre, terminalia arjuna, azadirachta indica, tinospora cordifolia, metronidazole, amphotericin B, clotrimazole, fluconazole, haloprogin, ketoconazole, griseofulvin, itraconazole, terbinafin·HCl, econazole·HNO <sub>3</sub> , miconazole, nystatin, oxiconazole·HNO <sub>3</sub> , sulconazole·HNO <sub>3</sub> , cetirizine·2HCl, dexamethasone, hydrocortisone, prednisolone, cortisone, catechin and its derivatives, glycyrrhizin, glycyrrhizic acid, betamethasone, <b>ludroeortisone</b> <b>fludrocortisone</b> ·acetate, flunisolide, fluticasone·propionate, methyl prednisolone, somatostatin, lispro, glucagon, proinsulin, insoluble insulins, acarbose, chlorpropamide, glipizide, glyburide, metformin·HCl,		

<b>1. Amendment to Page 25, Line 13 to Page 27, Line 9</b>			
<b>Date</b>	<b>Spec Change</b>	<b>Support</b>	<b>Objection</b>
	repaglinide, tolbutamide, amino acid, colchicine, sulfinpyrazone, allopurinol, piroxicam, tolmetin sodium, indomethacin, ibuprofen, diflunisal, mefenamic acid, naproxen, and trientine.		
Response filed February 28, 2006, to OA dated 12/09/05	The invention contemplates the use of a broad range of pharmaceutical compounds. Non-limiting examples include hormones, hormone antagonists, analgesic, antipyretics, anti-inflammatory drugs, immunoactive drugs, antineoplastic drugs, antibiotics, anti-inflammatory agents, sympathomimetic drugs, anti-infective drugs, anti-tumor agents, and anesthetics. Further non-limiting examples include drugs that target or effect the gastrointestinal tract, liver, cardiovascular system, and respiratory system. Further non-limiting examples of pharmaceutical compounds include insulin, heparin, calcitonin, ampicillin, octreotide, sildenafil citrate, calcitriol, dihydrotachysterol, apomorphine, yohimbine, trazadone, acyclovir, amantadine·HCl, rimantadine·HCl, cidofovir, delavirdine·mesylate, didanosine, famciclovir, foscarnet sodium, fluorouracil, ganciclovir sodium, idoxuridine, interferon- $\alpha$ , lamivudine, nevirapine, penciclovir, ribavirin, stavudine, trifluridine, valacyclovir·HCl, zalcitabine, zidovudine, indinavir·H <sub>2</sub> SO <sub>4</sub> , ritonavir, nelfinavir·CH <sub>3</sub> SO <sub>3</sub> H, saquinavir·CH <sub>3</sub> SO <sub>3</sub> H, d-penicillamine, chloroquine, hydroxychloroquine, aurothioglucose, gold sodium thiomalate, auranofin levamisole, <u>dacarbazine</u> <u>sodium</u>	Applicant respectfully asserts that expanding "DTC" to dacarbazine was an error made without deceptive intent. On February 28, 2006, Applicant furnished the Examiner with several documents that establish that one of ordinary skill in the art, at the time the instant application was filed, would have recognized that DTC is an abbreviation for sodium diethyldithiocarbamate. See Response filed February 28, 2006.	Pending Approval

1. Amendment to Page 25, Line 13 to Page 27, Line 9			
Date	Spec Change	Support	Objection
	<p><u>diethyldithiocarbamate</u>, isoprinosine, methyl inosine monophosphate, muramyl dipeptide, diazoxide, hydralazine·HCl, minoxidil, dipyridamole, isoxsuprine·HCl, niacin, nylidrin·HCl, phentolamine, doxazosin·CH<sub>3</sub>SO<sub>3</sub> H, prazosin·HCl, terazocin·HCl, clonidine·HCl, nifedipine, molsidomine, amiodarone, acetylsalicylic acid, verapamil, diltiazem, nisoldipine, isradipine, bepridil, isosorbide-dinitrate, pentaerythritol-tetranitrate, nitroglycerin, cimetidine, famotidine, nizatidine, ranitidine, lansoprazole, omeprazole, misoprostol, sucralfate, metoclopramide·HCl, erythromycin, bismuth compound, alprostadil, albuterol, pirbuterol, terbutaline·H<sub>2</sub>SO<sub>4</sub>, salmetrol, aminophylline, dyphylline, ephedrine, ethylnorepinephrine, isoetharine, isoproterenol, metaproterenol, nedocromil, oxtriphylline, theophylline, bitolterol, fenoterol, budesonide, flunisolide, beclomethasone-dipropionate, fluticasone-propionate, codeine, codeine sulfate, codeine phosphate, dextromethorphan·HBr, triamcinolone-acetonide, montelukast sodium, zafirlukast, zileuton, cromolyn sodium, ipratropium bromide, nedocromil sodium benzonate, diphenhydramine·HCl, hydrocodone-bitartarate, methadone·HCl, morphine sulfate, acetylcysteine, guaifenesin, ammonium carbonate, ammonium chloride, antimony potassium tartarate, glycerin, terpin-hydrate, colfosceril palmitate, atorvastatin·calcium, cervastatin·sodium, fluvastatin·sodium, lovastatin, pravastatin·sodium,</p>		

**1. Amendment to Page 25, Line 13 to Page 27, Line 9**

Date	Spec Change	Support	Objection
	simvastatin, picrorrhiza kurroa, andrographis paniculata, moringa oleifera, albizzia lebeck, adhatoda vasica, curcuma longa, momordica charantia, gymnema sylvestre, terminalia arjuna, azadirachta indica, tinosporia cordifolia, metronidazole, amphotericin B, clotrimazole, fluconazole, haloprogin, ketoconazole, griseofulvin, itraconazole, terbinafin·HCl, econazole·HNO <sub>3</sub> , miconazole, nystatin, oxiconazole·HNO <sub>3</sub> , sulconazole·HNO <sub>3</sub> , cetirizine·2HCl, dexamethasone, hydrocortisone, prednisolone, cortisone, catechin and its derivatives, glycyrrhizin, glycyrrhizic acid, betamethasone, fludrocortisone·acetate, flunisolide, fluticasone·propionate, methyl prednisolone, somatostatin, lispro, glucagon, proinsulin, insoluble insulins, acarbose, chlorpropamide, glipizide, glyburide, metformin·HCl, repaglinide, tolbutamide, amino acid, colchicine, sulfipyrazone, allopurinol, piroxicam, tolmetin sodium, indomethacin, ibuprofen, diflunisal, mefenamic acid, naproxen, and trientine.		

**2. Amendment to Page 53, Lines 1-5**

Date	Spec Change	Support	Objection
Response filed July 3, 2003, to OA Dated 12/31/02.	<u>Example VIII:</u> Mixture Solution  The formulations of Examples VIII, IX, <u>X</u> , <u>XI</u> , and <u>XXII</u> include <b>aqueous soluble bismuth sulfatechelate</b> . In each of these examples, solution dosage forms were prepared by adding an amount of an ammonium salt of bismuth sulfate sufficient to provide the indicated amount of bismuth sulfate.	Applicant respectfully asserts that support for the addition of Examples XI, and XII to this list may be found at 56:10-11 and 56:10-11, respectively. Support for the expression “aqueous soluble” may be found in first sentence of each example, i.e., the final compositions were free of precipitates. Applicant respectfully asserts that one of ordinary skill in the art having the benefit of the instant disclosure would recognize that chelate would form in solution.	Objected to.
Response filed August 2, 2005, to OA Dated 02/03/05	<u>Example VIII:</u> Mixture Solution  The formulations of Examples VIII, IX, X, XI, and XII include aqueous soluble bismuth <b>chelatesulfate</b> . In each of these examples, solution dosage forms were prepared by adding an amount of an ammonium salt of bismuth sulfate sufficient to provide the indicated amount of bismuth sulfate.	Applicant here withdrew the previous amendment to recite “chelate.” Since this amendment restores the text to the original expression, it is necessarily supported by the application as originally filed.	Objected to.
Response filed February 28, 2006, to OA dated 12/09/05	<u>Example VIII:</u> Mixture Solution  The formulations of Examples VIII, IX, <u>X</u> , <u>XI</u> , and <u>XII</u> include <b>aqueous soluble bismuth chelatesulfate</b> . In each of these examples, solution dosage forms were prepared by adding an amount	Applicant here withdrew the previous amendment to recite “aqueous soluble” and “chelate.” Since this amendment restores the text to the original expression, it is necessarily supported by the application as originally filed.	Pending Approval

**2. Amendment to Page 53, Lines 1-5**

Date	Spec Change	Support	Objection
	of an ammonium salt of bismuth sulfate sufficient to provide the indicated amount of bismuth sulfate.		

**3. Amendment to Page 53, Lines 6-14**

Date	Spec Change	Support	Objection
Response filed July 3, 2003, to OA Dated 12/31/02.	<p>Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected desired range of pH values.</p> <p>UDCA                                5 g CDCA                                5 g Bismuth <u>eitratesulfate</u>        5 g Corn syrup solid                  260 g Citric acid                        q.s. Purified water to make            1.0 L</p>	Applicant respectfully asserts that support for this amendment may be found earlier in the same example ( <i>i.e.</i> , at Page 53, Lines 1-5).	Objection withdrawn in OA mailed 05/17/06

**4. Amendment to Page 53, Lines 15-19**

Date	Spec Change	Support	Objection
Response filed July 3, 2003, to OA Dated 12/31/02.	The UDCA and CDCA were first dissolved in 1.5 mL of a 1N NaOH solution. Next, to the resulting clear solution were added the bismuth <b>eitratesulfate</b> and 150 mL of water. Then, the corn syrup solid was added portion by portion with vigorous agitation. The resulting solution was titrated to pH 4 with citric acid. Purified water was added to adjust the total volume to 1.0 L.	Applicant respectfully asserts that support for this amendment may be found earlier in the same example ( <i>i.e.</i> , at Page 53, Lines 1-5).	Objection withdrawn in OA mailed 05/17/06

5. Amendment to Page 54, Lines 1-10															
Date	Spec Change	Support	Objection												
Response filed July 3, 2003, to OA Dated 12/31/02.	<p><u>Example IX:</u> UDCA Syrup (20 g UDCA/L) Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected desired range of pH values.</p> <table><tbody><tr><td>UDCA</td><td>20 g</td></tr><tr><td>1 N NaOH</td><td>60 mL</td></tr><tr><td>Maltodextrin</td><td>700 g</td></tr><tr><td>Bismuth <del>citratesulfate</del></td><td>4 g</td></tr><tr><td>Citric acid or lactic acid</td><td>q.s.</td></tr><tr><td>Purified water to make</td><td>1.0 L</td></tr></tbody></table>	UDCA	20 g	1 N NaOH	60 mL	Maltodextrin	700 g	Bismuth <del>citratesulfate</del>	4 g	Citric acid or lactic acid	q.s.	Purified water to make	1.0 L	Applicant respectfully asserts that support for this amendment may be found in preceeding example ( <i>i.e.</i> , at Page 53, Lines 1-5).	Objection withdrawn in OA mailed 05/17/06
UDCA	20 g														
1 N NaOH	60 mL														
Maltodextrin	700 g														
Bismuth <del>citratesulfate</del>	4 g														
Citric acid or lactic acid	q.s.														
Purified water to make	1.0 L														

**6. Amendment to Page 55, Lines 1-10**

Date	Spec Change	Support	Objection												
Response filed July 3, 2003, to OA Dated 12/31/02.	<p><u>Example X:</u> UDCA Syrup (20 g UDCA/L) Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected desired range of pH values.</p> <table><tbody><tr><td>UDCA</td><td>20 g</td></tr><tr><td>1 N NaOH</td><td>60 mL</td></tr><tr><td>Corn syrup solid</td><td>1,050 g</td></tr><tr><td>Bismuth <u>etbratesulfate</u></td><td>4 g</td></tr><tr><td>Citric acid or lactic acid</td><td>q.s.</td></tr><tr><td>Purified water to make</td><td>1 L</td></tr></tbody></table>	UDCA	20 g	1 N NaOH	60 mL	Corn syrup solid	1,050 g	Bismuth <u>etbratesulfate</u>	4 g	Citric acid or lactic acid	q.s.	Purified water to make	1 L	Applicant respectfully asserts that support for this amendment may be found in Example VIII ( <i>i.e.</i> , at Page 53, Lines 1-5).	Objection withdrawn in OA mailed 05/17/06
UDCA	20 g														
1 N NaOH	60 mL														
Corn syrup solid	1,050 g														
Bismuth <u>etbratesulfate</u>	4 g														
Citric acid or lactic acid	q.s.														
Purified water to make	1 L														

**7. Amendment to Page 56, Lines 1-9**

Date	Spec Change	Support	Objection												
Response filed July 3, 2003, to OA Dated 12/31/02.	<p><u>Example XI:</u> UDCA Thick Syrup (30 g UDCA/L)</p> <p>Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected desired range of pH values.</p> <table><tr><td>UDCA</td><td>30 g</td></tr><tr><td>1 N NaOH</td><td>90 mL</td></tr><tr><td><b>Bismuth sulfate</b></td><td><b>4 g</b></td></tr><tr><td>Maltodextrin</td><td>1,050 g</td></tr><tr><td>Citric acid or lactic acid</td><td>50 g</td></tr><tr><td>Purified water to make</td><td>1.0 L</td></tr></table>	UDCA	30 g	1 N NaOH	90 mL	<b>Bismuth sulfate</b>	<b>4 g</b>	Maltodextrin	1,050 g	Citric acid or lactic acid	50 g	Purified water to make	1.0 L	Applicant respectfully asserts that support for this amendment may be found in Example VIII ( <i>i.e.</i> , at Page 53, Lines 1-5).	Objected to.
UDCA	30 g														
1 N NaOH	90 mL														
<b>Bismuth sulfate</b>	<b>4 g</b>														
Maltodextrin	1,050 g														
Citric acid or lactic acid	50 g														
Purified water to make	1.0 L														
Response filed August 2, 2005, to OA Dated 02/03/05.	<p><u>Example XI:</u> UDCA-Thick Syrup (30 g UDCA/L)</p> <p>Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected desired range of pH values.</p> <table><tr><td>UDCA</td><td>30 g</td></tr><tr><td>1 N NaOH</td><td>90 mL</td></tr><tr><td><b>Bismuth sulfate</b></td><td><b>4 g</b></td></tr><tr><td>Maltodextrin</td><td>1,050 g</td></tr><tr><td>Citric acid or lactic acid</td><td>50 g</td></tr><tr><td>Purified water to make</td><td>1.0 L</td></tr></table>	UDCA	30 g	1 N NaOH	90 mL	<b>Bismuth sulfate</b>	<b>4 g</b>	Maltodextrin	1,050 g	Citric acid or lactic acid	50 g	Purified water to make	1.0 L	Applicant here withdrew the previous amendment to recite "bismuth sulfate." Since this amendment restores the text to the original expression, it is necessarily supported by the application as originally filed.	Objection withdrawn in OA mailed 05/17/06
UDCA	30 g														
1 N NaOH	90 mL														
<b>Bismuth sulfate</b>	<b>4 g</b>														
Maltodextrin	1,050 g														
Citric acid or lactic acid	50 g														
Purified water to make	1.0 L														

**8. Amendment to Page 57, Lines 1-9**

Date	Spec Change	Support	Objection												
Response filed July 3, 2003, to OA Dated 12/31/02.	<p><u>Example XII:</u> UDCA Thick Syrup (30 g UDCA/L)</p> <p>Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected desired range of pH values.</p> <table><tr><td>UDCA</td><td>30 g</td></tr><tr><td>1 N NaOH</td><td>90 mL</td></tr><tr><td><b>Bismuth sulfate</b></td><td><b>4 g</b></td></tr><tr><td>Corn syrup solid</td><td>1,500 g</td></tr><tr><td>Citric acid or lactic acid</td><td>50 g</td></tr><tr><td>Purified water to make</td><td>1.0 L</td></tr></table>	UDCA	30 g	1 N NaOH	90 mL	<b>Bismuth sulfate</b>	<b>4 g</b>	Corn syrup solid	1,500 g	Citric acid or lactic acid	50 g	Purified water to make	1.0 L	Applicant respectfully asserts that support for this amendment may be found in Example VIII ( <i>i.e.</i> , at Page 53, Lines 1-5).	Objected to.
UDCA	30 g														
1 N NaOH	90 mL														
<b>Bismuth sulfate</b>	<b>4 g</b>														
Corn syrup solid	1,500 g														
Citric acid or lactic acid	50 g														
Purified water to make	1.0 L														
Response filed August 2, 2005, to OA Dated 02/03/05.	<p><u>Example XII:</u> UDCA-Thick Syrup (30 g UDCA/L)</p> <p>Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected desired range of pH values.</p> <table><tr><td>UDCA</td><td>30 g</td></tr><tr><td>1 N NaOH</td><td>90 mL</td></tr><tr><td><b>Bismuth sulfate</b></td><td><b>4 g</b></td></tr><tr><td>Corn syrup solid</td><td>1,500 g</td></tr><tr><td>Citric acid or lactic acid</td><td>50 g</td></tr><tr><td>Purified water to make</td><td>1.0 L</td></tr></table>	UDCA	30 g	1 N NaOH	90 mL	<b>Bismuth sulfate</b>	<b>4 g</b>	Corn syrup solid	1,500 g	Citric acid or lactic acid	50 g	Purified water to make	1.0 L	Applicant here withdrew the previous amendment to recite "bismuth sulfate." Since this amendment restores the text to the original expression, it is necessarily supported by the application as originally filed.	Objection withdrawn in OA mailed 05/17/06
UDCA	30 g														
1 N NaOH	90 mL														
<b>Bismuth sulfate</b>	<b>4 g</b>														
Corn syrup solid	1,500 g														
Citric acid or lactic acid	50 g														
Purified water to make	1.0 L														

9. Amendment to Page 58, Lines 1-5			
Date	Spec Change	Support	Objection
Response filed July 3, 2003, to OA Dated 12/31/02.	<u>Example XIII:</u> UDCA Paste (45 g UDCA/L) The formulations of Examples XIII, XIV, XV, <b>XVI, XVII, and XVIII</b> include bismuth citrate <b>as chelate</b> . In each of these examples, solution dosage forms were prepared by adding an amount of an ammonium salt of bismuth citrate sufficient to provide the indicated amount of bismuth citrate.	Applicant respectfully asserts that support for the addition of Example XVIII to this list may be found at 66:11-13. Applicant respectfully asserts that one of ordinary skill in the art having the benefit of the instant disclosure would recognize that chelate would form in solution.	Objected to.
Response filed August 2, 2005, to OA Dated 02/03/05.	<u>Example XIII:</u> UDCA-Paste (45 g UDCA/L) The formulations of Examples XIII, XIV, XV, XVI, XVII, and XVIII include bismuth citrate <b>as chelate</b> . In each of these examples, solution dosage forms were prepared by adding an amount of an ammonium salt of bismuth citrate sufficient to provide the indicated amount of bismuth citrate.	Applicant here withdrew the previous amendment to recite "chelate." Since this amendment restores the text to the original expression, it is necessarily supported by the application as originally filed.	Objection withdrawn in OA mailed 05/17/06
Response filed April 25, 2007, to OA Dated 01/25/07.	<u>Example XIII:</u> UDCA-Paste (45 g UDCA/L) The formulations of Examples XIII, XIV, XV, XVI, <b>XVII</b> , and XVIII include bismuth citrate. In each of these examples, solution dosage forms were prepared by adding an amount of an ammonium salt	Applicant realized upon preparing the instant Response that Example XVII was added to this list in error. See 62:21-22 (stating that a composition of Example VIII was used). Accordingly, Applicant has herein withdrawn the previous amendment to add Example XVII to this list. Since this amendment restores the text to	

9. Amendment to Page 58, Lines 1-5			
Date	Spec Change	Support	Objection
	of bismuth citrate sufficient to provide the indicated amount of bismuth citrate.	the original expression, it is necessarilyly supported by the application as originally filed.	

**10. Amendment to Page 60, Lines 1-9**

Date	Spec Change	Support	Objection												
Response filed July 3, 2003, to OA Dated 12/31/02.	<p><u>Example XIV:</u> UDCA Paste (45 g UDCA/L) Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected desired range of pH values.</p> <table><tr><td>UDCA</td><td>45 g</td></tr><tr><td>1 N NaOH</td><td>135 mL</td></tr><tr><td><b><u>Bismuth citrate</u></b></td><td><b><u>10 g</u></b></td></tr><tr><td>Corn syrup solid</td><td>2,300 g</td></tr><tr><td>Citric acid or lactic acid</td><td>50 g</td></tr><tr><td>Purified water to make</td><td>1.0 L</td></tr></table>	UDCA	45 g	1 N NaOH	135 mL	<b><u>Bismuth citrate</u></b>	<b><u>10 g</u></b>	Corn syrup solid	2,300 g	Citric acid or lactic acid	50 g	Purified water to make	1.0 L	Applicant respectfully asserts that support for this amendment may be found in Example XIII ( <i>i.e.</i> , at Page 58, Lines 1-5).	Objected to.
UDCA	45 g														
1 N NaOH	135 mL														
<b><u>Bismuth citrate</u></b>	<b><u>10 g</u></b>														
Corn syrup solid	2,300 g														
Citric acid or lactic acid	50 g														
Purified water to make	1.0 L														
Response filed August 2, 2005, to OA Dated 02/03/05.	<p><u>Example XIV:</u> UDCA Paste (45 g UDCA/L) Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected desired range of pH values.</p> <table><tr><td>UDCA</td><td>45 g</td></tr><tr><td>1 N NaOH</td><td>135 mL</td></tr><tr><td><b><u>Bismuth citrate</u></b></td><td><b><u>10 g</u></b></td></tr><tr><td>Corn syrup solid</td><td>2,300 g</td></tr><tr><td>Citric acid or lactic acid</td><td>50 g</td></tr><tr><td>Purified water to make</td><td>1.0 L</td></tr></table>	UDCA	45 g	1 N NaOH	135 mL	<b><u>Bismuth citrate</u></b>	<b><u>10 g</u></b>	Corn syrup solid	2,300 g	Citric acid or lactic acid	50 g	Purified water to make	1.0 L	Applicant here withdrew the previous amendment to recite "bismuth sulfate." Since this amendment restores the text to the original expression, it is necessarily supported by the application as originally filed.	Objection withdrawn in OA mailed 05/17/06
UDCA	45 g														
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Purified water to make	1.0 L														

In view of the orderly presentation of the amendments made to the specification set forth in the preceding chart, it is believed that a substitute specification is not required. Since

none of the changes made to the specification constitute new matter, Applicant respectfully requests withdrawal of this objection.

**Double Patenting Rejection**

According to the Office Action, Claims 138-140, 142-148 and 152-155 have been provisionally rejected over Claims 1-35 of related Patent No. 6,251,428 (hereinafter “‘428 patent”) based on the judicially created double patenting doctrine. The Office Action states that the subject matter claimed in the instant application is fully disclosed in the referenced patent.

Applicants respectfully traverse the rejection. However, to reduce the cost and time required to obtain patent protection, a Terminal Disclaimer filed in compliance with 37 C.F.R. 1.321 is attached hereto. The Terminal Disclaimer is offered in the event the Examiner converts the provisional rejection to a rejection based on non-statutory double patenting grounds. The ‘428 patent and the instant patent application are commonly owned by Seo Hong Yoo.

### CONCLUSION

Applicant has made an earnest effort to place this case in condition for allowance in light of the amendments and remarks set forth above. Applicant respectfully requests reconsideration of the pending claims.

Applicant authorizes the Commissioner to charge \$65.00 for the Statutory Disclaimer fee. Applicant believes there are no additional fees due at this time, however, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment to Deposit Account No. 50-2148 of Baker Botts L.L.P.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicant's attorney at (512) 322-2647.

Respectfully submitted,  
BAKER BOTTS, L.L.P.  
Attorneys for Applicant



Guy F. Birkenmeier  
Reg. No. 52,622

Date: April 25, 2007

CORRESPONDENCE ADDRESS:

Customer No. **31625**  
(512) 322-2647  
(512) 322-8383 (fax)